Screening for Diabetic Retinopathy by General Practitioners: Ophthalmoscopy or Retinal Photography as 35 mm Colour Transparencies?

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In order to assess the relative ability of general practitioners (GPs) to detect diabetic retinopathy (DR), especially sight-threatening diabetic retinopathy (STDR) by direct ophthalmoscopy or by examining, on a separate occasion, retinal images as 35 mm colour transparencies, a South and Mid Wales primary care-based study was performed in four general practices (six GPs). The participating GPs were provided with standardized training and equipment. Both methods were compared to the 'reference' grade of DR provided by the Diabetic Retinopathy Reading Centre (London), based on the same retinal images. Ophthalmoscopy and retinal photography (Canon CR4 45NM) with mydriasis were all practice based. The clinical assessments were based on a protocol developed for screening for DR in Europe. A total of 996 people with diabetes were identified, representing a prevalence of known diabetes of 2.1 %. After exclusions on medical grounds, 897 patients were available for screening, of whom 605 (68 %) were photographed. Based on the retinal images, the reference centre identified DR in 43 % and STDR in 14.4 %. In total, 597 valid comparisons between GPs and the reference centre were obtained; of these, 462 (77 %) were high quality photographs which were used in subsequent analysis. The sensitivity for detecting any DR increased from 62.6 % (95 % CI 55.9–69.4) with ophthalmoscopy to 79.2 % (95 % CI 73.6–84.9) using retinal photographs, specificity remaining essentially unchanged at 75.0 (95 % CI 69.5–80.5) and 73.5 % (95 % CI 68.0–79.1) with the positive predictive value (PPV) increasing from 67.2 (95 % CI 60.4–74.0) to 71.0 % (95 % CI 65.0–77.0), respectively. The detection of STDR sensitivity increased from 65.7 (95 % CI 54.4–77.1) with ophthalmoscopy alone to 87.3 % (95 % CI 79.4–95.2) based on retinal photographs with specificity falling from 93.8 (95 % CI 91.4–96.3) to 84.8 % (95 % CI 81.2–88.5) and PPV from 65.7 (95 % CI 54.4–77.1) to 51.2 % (95 % CI 42.1–60.3), respectively. We conclude that the use of standardized 35 mm colour transparency retinal photographs for screening by trained GPs in a primary care setting achieves an acceptable detection rate (>87 %) for STDR, contrasting with ophthalmoscopy alone (66 %), which was below the proposed UK standard of 80 %. © **1998 John Wiley & Sons, Ltd.**

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Introduction

All people with diabetes are at risk of developing diabetic retinopathy (DR) and despite the irrefutable clinical and economic benefits of early detection and timely photocoagulation,[1–4] it continues to represent the most common cause of blindess during the working years.[5,6] A recent review of patients registered blind due to diabetes in the UK revealed that 50 % had had no prior eye examination, despite being known to have diabetes.[7] In the absence of an agreed method of screening, various modalities are therefore in use,[8–14] although often unsupported by quality assurance procedures. As a consequence of one of the key objectives of the St Vincent Declaration to reduce new blindness due to

Abbreviations: DR diabetic retinopathy, GP general practitioner, STDR sight threatening diabetic retinopathy

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diabetes by one-third or more,[15] a co-operative European initiative has led to the development of a protocol for screening for diabetic retinopathy.[16]

Since up to 50 % of people with diabetes rarely or never attend hospital diabetic clinics[17] the role of the general practitioner (GP),[18–20] ophthalmic opticians,[21,22] and technicians[23] as primary screeners has been examined. Whereas effectiveness of screening by GPs using ophthalmoscopy alone is known to be poor,[18] an initial pilot study suggested considerable improvement in the detection of sight threatening diabetic retinopathy (STDR) using retinal photographs as 35 mm colour transparences.[24] The current study was designed to explore this further in a community-based study involving rural and urban practices.

Methods

The study was conducted in four group general practices, two urban (Newport and Cardiff) and two rural (Brecon and Abergaveny), in South and Mid Wales. Criteria for recruitment to the study required each of the practices to have a known prevalence rate for diabetes of >1.8 %. Data from our pilot study[24] indicated that a sample size of 600 subjects would be required in order to estimate the prevalence of retinopathy with confidence limits of ± 3 %, and to obtain confidence limits on the sensitivity of detection of STDR of ± 7 %.

All six participating GPs underwent a training session (6 hours) relating to DR, which included eye examination techniques (visual acuity and ophthalmoscopy) and the grading of DR. They were provided with standardized equipment for eye examination (Welch Allyn ophthalmoscope and Snellen 3 metre visual acuity charts) and a slide viewing box (Slidex). Practice-based diabetes registers were checked and all patients, were sent information about the study by the project team. Weekly clinics were held in each of the four practices over an 11-month period, with the Canon CR4 45NM fundus camera transported to the GP's office on each of the study clinic days.

On each of the study days, visual acuity was determined prior to pupil dilation. For this study, patients with glaucoma on treatment or a history of a previous anterior lens implant were excluded. Mydriasis was induced using 1 % tropicamide drops, at least 10 minutes before ophthalmoscopic examination by the GP. Retinal photography followed, to obtain two 45° fields per eye, one centred on the macula and the other centred nasal to the optic disc. All the retinal photographs were taken by one person (study optometrist—SW), using the Canon CR4 45NM retinal camera and Kodak Ektachrome Elite 100 film to produce 35 mm colour transparencies mounted as slides. The anomymized slides were viewed by the GPs at a later date, each GP only grading those from his/her own practice. All retinal photographs were also independently graded by two independent readers at the Diabetic Retinopathy Reading Centre, Royal Postgraduate Medical School, London, to serve as the 'reference' standard for both clinical grade of diabetic retinopathy per eye and quality level of each colour transparency. The quality level was based on EURODIAB criteria[25] as follows:

Level 1: Excellent—full field photography, picture definition good, lesions easily discernible as present or not present.
Level 2: Good—3/4 field photograph, picture definition good, lesions easily discernible as present or not present.
Level 3: Fair—1/2 field photograph, picture definition good, lesion discrimination uncertain due to light or other aberration, e.g.. eyelashes.
Level 4: Poor—less than 1/2 field photography, picture definition poor, lesion discrimination poor.

The clinical grading system adopted for the study (Table 1) was derived from the European guidelines[16] and agreed with the Retinopathy Reading Centre, Royal Postgraduate Medical School, London, as was the independent quality assessment of the retinal photographs.

The study protocol was approved by the local ethical committees for the study practice areas. All patients were provided with an information sheet and gave written informed consent before acceptance into the study. All fundal photographs were viewed by one of the clinical co-ordinators (DRO, RLG) within 1 week of being developed. Where STDR had been missed during ophthalmoscopy, GPs were notified and patients referred according to guidelines provided for the study.

The data were analysed using SPSS for Windows, Version 6.0. As a reference standard was being employed to evaluate a diagnostic test used as a screening procedure, sensitivity (percentage of positives correctly identified), specificity (percentage of negatives correctly identified), and positive predictive value (percentage of true positives, PPV) were used as the appropriate statistics. The 95 % confidence intervals were calculated using the Confidence Intervals Analysis (CIA) computer software program.

Results

The four participating general practices had a combined list of 47 462 people, with 996 (2.1 %) identified as having diabetes. Excluding subjects who had recently died or moved reduced the number of diabetic patients to 959; i.e. 2.0 % of the total list. Sixty-two patients (6.5 %) were excluded from screening by their GP for medical reasons, such as terminal illness, registered blindness or the presence of dementia. Poor vision or the presence of cataract were not grounds for exclusion. This left 897 subjects available for screening.

In total, 613 patients attended for screening, of whom 605 were photographed; 343 (56.0 %) of those who attended were male, and 502 (81.9 %) had Type 2 diabetes mellitus (NIDDM). The mean (standard deviation) age of insulin-treated patients (Type 1 and

Table 1. Welsh Community Diabetic Retinopathy Study Clinical groupings

Clinical grouping and description
0 No diabetic retinopathy
NON-SIGHT THREATENING DIABETIC RETINOPATHY
1 Non-proliferative retinopathy: non-PDR (mild) Occasional haemorrhages and/or microaneurysms (red 'dots and blots') and hard exudate not within 1 disc diameter of the macula centre. One soft exudate (cotton wool spot) per eye not associated with preproliferative lesions.
2a Non-proliferative retinopathy: non-PDR (moderate) without macular involvement Large circinate or plaque hard exudates within the major temporal vascular arcades but not <1 disc diameter from macula centre.
SIGHT THREATENING DIABETIC RETINOPATHY
2b Non-proliferative retinopathy: NPDR (moderate) with macular involvement—maculopathy Haemorrhages and/or hard exudates within the major temporal vascular arcades <1 disc diameter from macula centre.
3 Preproliferative retinopathy (PPDR) Venous irregularities (beading, reduplication, loops) and/or multiple haemorrhages, and/or multiple soft exudate (cotton wool spots) and/or intraretinal microvascular abnormalities (IRMA).
4 Proliferative retinopathy (PDR) New vessels on the disc or elsewhere in the retina. Pre-retinal haemorrhage and/or fibrous tissue.
5 Advanced diabetic eye disease (ADED) Vitreous haemorrhage and/or extensive fibrosis, and/or recent retinal detachment and/or rubeosis iridis.
6 Presence of photocoagulation from previous treatment

Type 2) was 52.0 (19.8) years and of other Type 2 patients 66.3 (10.8) years. There were no systematic differences between the four practices. According to the reference centre's grading of all 605 patients photographed (Table 2), there was no evidence of retinopathy in 55.7 % (95 % CI: 51.7–59.7 %) of the subjects; non-sight threatening background diabetic retinopathy in 28.6 % (95 % CI: 25.0–32.2 %) and sight threatening retinopathy in 14.4 % (95 % CI: 11.6–17.2 %); 1.3 % of photographs were not gradeable. The prevalence of DR or STDR was consistent between urban and rural practices.

Seventy-eight per cent of all photographs (1888 out of 2420) were graded as being of excellent or good quality. Eight patients' photographs (1.5 %) were of poor quality and therefore unsuitable for grading due to media opacification or for technical reasons. Of the remaining 597 patients, 77 % had macular pictures from both eyes of excellent (level 1) or good (level 2) quality, 16 % had good or excellent quality photographs of only one macula with 7 % of fair or poor quality.

The GPs' performance in identifying diabetic retinopathy using ophthalmoscopy and 35 mm slides compared with the reference standard was based on the 462 subjects in whom excellent or good quality macular fields were obtained from both eyes, detailed in Tables 3 and 4, respectively. Completely agreement was obtained in 61.3 % using ophthalmoscopy and 65.8 % using 35 mm slides. The GPs' sensitivity for detecting the presence of any diabetic retinopathy increased from 62.6 % (95 % CI: 55.9–69.4) with ophthalmoscopy to 79.2 % (95 % CI: 73.6–84.9) with 35 mm slides, a difference of 16.6 % (95 % CI. 8.0–25.2). Specificity remained unchanged at 75.0 % (95 % CI: 69.5–80.5) and 73.5 % (95 % CI: 68.0–79.1), respectively, and the positive predictive value of the screening increased from 67.2 % (95 % CI: 60.4–74.0) to 71.0 % (95 % CI: 65.2–

Table 2. Prevalence of diabetic retinopathy according to reference standard

Retinopathy type	Urban number	Urban % (95 % CI)	Rural number	Rural % (95 % CI)	Total number	Total % (95 % CI)
None	144	54.1 (48.1–60.1)	193	56.9 (51.7–62.2)	337	55.7 (51.7–59.7)
BDR	85	32.0 (26.4–37.6)	88	26.0 (21.3–30.6)	173	28.6 (25.0–32.2)
STDR	33	12.4 (8.4–16.4)	54	15.9 (12.0–19.8)	87	14.4 (11.6–17.2)
Not graded	4	1.5	4	1.2	8	1.3
Total	266	100	339	100	605	100

Background diabetic retinopathy (BDR) = grade 1 or grade 2a diabetic retinopathy. Sight threatening diabetic retinopathy (STDR) = grade 2b and above (see Figure 1).

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Table 3(a). Details of GP ophthalmoscopy grading vs reference standard

RPMS→ GPs ↓	0	1	2a	2b	3	4	5	No grade	Total
0	189	73	0	1	1	0	2	0	266
1	47	38	1	4	5	1	0	0	96
2a	9	6	1	3	7	0	0	0	26
2b	6	13	1	10	16	3	0	0	49
3	0	2	0	2	6	2	1	0	13
4	1	0	0	0	0	2	0	0	3
5	0	1	0	0	1	1	2	0	5
No grade	1	1	0	0	2	0	0	0	4
Total	253	134	3	20	38	9	5	0	462

Table 3(b). Summary of GP ophthalmoscopy grading vs reference standard

	RPMS→			
GP↓	None	BDR	STDR	Total
None	189	73	4	266
BDR	56	46	20	122
STDR	7	17	46	70
Total	252	136	70	458[a]

Four photographs were given no grade.

Table 4(a). Details of GP retinal photograph grading vs reference standard

RPMS→ GPs ↓	0	1	2a	2b	3	4	5	No grade	Total
0	186	42	0	0	1	0	0	0	229
1	37	44	1	0	2	0	0	0	84
2a	10	9	1	1	4	0	1	0	26
2b	17	32	1	15	18	2	1	0	86
3	0	3	0	3	12	4	1	0	23
4	1	3	0	0	1	1	0	0	6
5	2	0	0	0	0	2	2	0	6
No grade	0	1	0	1	0	0	0	0	2
Total	253	134	3	20	38	9	5	0	462

Table 4(b). Summary of GP retinal photograph grading vs reference standard

	RPMS→			
GP↓	None	BDR	STDR	Total
None	186	42	1	229
BDR	47	55	8	110
STDR	20	39	62	121
Total	253	136	71	460[a]

Two photographs were given no grade.

Table 5(a). Identification of any diabetic retinopathy by GPs compared to the reference standard

	Any lesions of DR (% with 95 % CI)		
	Ophthalmoscopy	Retinal photographs	Differences
Sensitivity	62.6 (55.9–69.4)	79.2 (73.6–84.9)	16.6
Specificity	75.0 (69.5–80.5)	73.5 (68.0–79.1)	1.5
PPV	67.2 (60.4–74.0)	7.10 (65.2–77.0)	3.8

PPV, positive predictive value.

77.0). Viewing the 35 mm slides increased the GPs' sensitivity for detecting STDR from 65.7 % (95 % CI: 54.4–77.1) with ophthalmoscopy to 87.3 % (95 % CI: 79.4–95.2), a difference of 21.6 % (95 % CI 8.1–35.2), accompanied by a fall in specificity from 93.8 % (95 % CI: 91.4–96.3) to 84.8 % (95 % CI: 81.2–88.5) and positive predictive value from 65.7 % (95 % CI: 54.4–77.1) to 51.2 % (95 % CI: 42.1–60.3), respectively (Table 5(b)). There were no significant differences between urban and rural GPs with respect to the detection of any DR or STDR.

Further analysis revealed that 32.4 % of patients with STDR were undergraded when using ophthalmoscopy alone, of whom 14 % were given non-urgent referral and 18.3 % were not referred to specialist services. In contrast when using the retinal photographs only 11 % of patients with STDR were undergraded, 8.5 % of whom received non-urgent referral and 2.8 % no referral. With ophthalmoscopy, overgrading to STDR occurred in 6.2 % of patients, 18 % of whom had no DR. Viewing the retinal photographs resulted in 15.1 % being overgraded to STDR. Drusen and age-related macular degeneration accounted for 37.3 % and microaneurysms in the macula area another 33.7 %, the remainder being myopic degeneration, reflective retina in young patients and exudate formation greater than one disc diameter from the fovea.

Table 5(b). Identification of sight threatening diabetic retinopathy by GPs compared to the reference standard

	Sight threatening DR (% with 95 % CI)		
	Ophthalmoscopy	Retinal photographs	Differences
Sensitivity	65.7 (54.4–77.1)	87.3 (79.4–95.2)	21.6
Specificity	93.8 (91.4–96.3)	84.8 (81.2–88.5)	9.0
PPV	65.7 (54.4–77.1)	51.2 (42.1–60.3)	14.5

PPV, positive predictive value.

Discussion

In view of the fact that a large proportion of people with diabetes (up to 50 %) never or rarely regularly attend hospital diabetic clinics in the UK,[17] any retinopathy screening service must utilize the resources of the primary health care sector. Evidence suggests that GPs as well as hospital doctors are poor in detecting sight threatening diabetic retinopathy by direct ophthalmoscopy alone.[9,13,18,20] A number of studies suggest that improvement is evident with training[26,27] and/or the concomitant use of retinal photography.[10,11,12,14,23,24] Most of these studies comparing ophthalmoscopy and retinal photography especially those in primary care have lacked validation.

We have attempted to avoid the limitations of earlier studies by conducting a community-based study in primary care practices with prevalence of diagnosed diabetes of approximately 2 %, examining patients both ophthalmoscopically and photographically on the same study day.

The prevalence of DR and STDR in our study (43.0 % and 14.4 %, respectively) is consistent with other studies using retinal photography in the form of 35 mm colour transparencies.[12] Other community-based studies employing ophthalmoscopy alone have found the prevalence of STDR to be much lower and even the combination of ophthalmoscopy and retinal photography as Polaroid prints a detection rate no higher than 8.5 % was observed.[13,23] The detection of STDR by direct ophthalmoscopy supplemented with Polaroid prints may be inferior to 35 mm transparencies even when used in isolation.

In this study using the Canon CR4 45NM retinal camera following mydriasis and with the same operator, almost 80 % of the images were deemed of excellent or good quality. Retinal photography increased the specificity and sensitivity of screening compared to ophthalmoscopy, with importantly, the sensitivity and specificity for detecting STDR also increasing. Our findings are similar to those recently reported from Liverpool, which achieved a sensitivity and specificity of 89 % and 86 %, respectively, using 35 mm colour transparencies in three fields for detecting sight threatening diabetic eye disease.[12] These observations are important in view of the proposed standards for retinopathy screening programmes in the UK, which recommends that screening modalities should have a sensitivity of at last 80 %, specificity of 95 % with a maximum 5 % technical failure rate.[14] Our study, and that from Liverpool,[12] therefore achieved the sensitivity target while closely approaching that required for specificity. This evidence is lacking for most other retinal screening techniques. In the Liverpool study, however, ophthalmoscopy was conducted by a registrar and photograph assessment by a clinical assistant, with no indication of levels of agreement and there were no data on photograph quality.

Another important finding in our study was the relatively low rate of undergrading when using the retinal images only (11.3 %) of STDR. Only 2 % of affected patients were not given urgent referral. This contrasted with 32.4 % of patients with STDR undergraded using ophthalmoscopy alone, of whom 18 % were not considered for referral. The reduction in specificity and positive predictive value for detecting STDR when using photographs, compared to ophthalmoscopy, was largely accounted for by misdiagnosis of degenerative macular changes (drusen) and maculopathy as microaneurysms within 1 disc diameter of the fovea, both amenable to correction with further education.

An essential element in any diabetic retinopathy screening programme is an efficient identification and re-call system. It has been suggested that, provided the method employed has a sensitivity of 60 % or greater, annual review will detect most sight threatening diabetic eye disease.[28] In this study the recruitment rate was only 68 %, despite all efforts by a dedicated project team. Continuation of the project has achieved a recruitment rate of 75 % over a 2-year period. This supports the need for adopting a screening method with a higher sensitivity as currently proposed for the UK.[14]

In summary, the results demonstrate that trained, motivated and well-equipped GPs can provide a primary care-based retinal screening service, using retinal photographs in the form of 35 mm colour transparencies with a Slidex viewer. In practice, this evaluation would be aided by the assessment of visual acuity, especially for maculopathy where the value of colour photographs alone would be limiting. As most patients already attend their GP for other aspects of diabetes care, the provision of eye screening services in the same setting may offer advantages to patients, especially in rural areas, by minimizing visits to other providers or sites. The doctors involved incidentially reported that the use of a clinically based system for grading of retinal photographs linked directly to management guidelines[16] helped improve their confidence in classifying lesions by giving them a structured format.

Commissioners of health services are required to make evidence-based decisions when considering service developments such as the introduction of screening for DR. The findings from this study demonstrate that properly trained and equipped primary screeners (GPs), employing community-based disease registers and 35 mm colour transparency retinal photographs, are capable of providing a diabetic retinopathy screening service to currently acceptable standards in a primary care setting. Until comparable evidence is produced to the contrary, direct ophthalmoscopy in primary care by GPs should be regarded as an inadequte method of screening for DR, especially STDR. Retinal photography should therefore become an intregral part of structured DR screening programmes based in primary care, and therefore available to all known diabetic patients. This model of care should receive serious consideration and be subject to further evaluation.

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